TECHNICAL INFORMATION PAPER

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DETERMINING ELIGIBILITY FOR EPR FUNDING OF A VYLEATER® VIAL DISPOSAL SYSTEM

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PURPOSE. To discuss and evaluate Environmental Program Requirements (EPR) funding eligibility for the purchase and use of a vial disposal system, such as the Vyleater, to reduce and consolidate certain laboratory hazardous wastes (HW).

REFERENCES. See Appendix A for a list of reference information.

POINTS OF MAJOR INTEREST AND FACTS.

Background.

Medical treatment facility (MTF) laboratories generate wastes to include, but not limited to, containers of unprocessed urine samples remaining after analysis is complete (a non-HW and non-regulated medical waste (non-RMW)), as well as cytology specimen vials containing approximately 20 milliliters (mL) of a methanol-based cyto-preservative solution (i.e., ThinPrep® PreservCyt®, an HW).

Urine samples are typically managed by personnel manually emptying the container to the sanitary sewer (via toilet or sink). Note, because of the potential for personally identifiable information (PII) on the empty container, some MTFs may mistakenly place them in the RMW for disposal rather than remove any patient information and place them in solid waste. However, the container (empty or full) is not RMW. The majority of RMW is autoclaved and landfilled, not incinerated, such that any PII information on the containers remains intact and legible. Placing non-RMW items in the RMW as a means to address PII is not authorized and depletes necessary RMW environmental funding.

There are two possible ways to manage the HW cytology specimen vials. One way is to place the intact vials and their liquid contents into a larger secondary container prior to disposal as an HW. This unnecessarily increases the volume of HW being managed and disposed of because the mass of each individual specimen vial is included (e.g., a 55-gallon drum of vials may only contain 3 to 4 gallons of hazardous waste liquid, but the entire contents of the drum must be managed as HW). Alternatively, personnel may manually open the vials and collect the cyto-preservative solution in a single larger container prior to disposal as a HW. [Note, this manual emptying process may increase the potential for spills and/or exposure of personnel to the HW being collected.] The

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emptied specimen vials are not subject to HW regulations and should be disposed as solid waste.

Use of Automated Vial Crushing/Shredding Equipment.

Automatic equipment, such as the Vyleater, is available to crush/shred small laboratory vials, separating the sample containers from their liquid contents. The equipment will automatically send plastic, glass, or metal vial fragments to one accumulation container for disposal as a solid waste while the vial contents will be sent to a separate destination, either another accumulation container (for HW) or connected to a drain for disposal to the sanitary sewer (for non-HW).

If the vials containing the HW cyto-preservative are currently managed intact when disposed by the MTF, the Vyleater will utilize waste consolidation to significantly reduce overall HW volume by eliminating the mass of the individual vials and collecting the liquid in one larger container, resulting in waste disposal cost savings. For both HW and non-HW, the equipment eliminates labor costs associated with laboratory personnel manually emptying the contents of the vials.

The MTF Environmental Science and Engineering Officer should be consulted in the planning phases of acquisition of the vial shredder to ensure compliance with all local and state environmental requirements.

Management of Vials of Hazardous Waste.

ThinPrep PreservCyt is a methanol-based preservative solution with a flashpoint of 27 °Celsius/81 °Fahrenheit. When disposed, the used solution is a characteristic ignitable HW, Environmental Protection Agency (EPA) HW number D001. For this reason, use of an explosion-proof model Vyleater is required to safely manage this waste.

Use of a vial shredder to consolidate waste from small sample vials into a larger container is not considered treatment by the EPA as long as the only function of the equipment is waste consolidation and no HW is released or altered during the process.

The optional internal flushing system accessory available for the Vyleater is not required and should not be used for the cyto-preservative waste or any other HW. Flushing the cyto-preservative would alter the waste stream (through dilution) and constitute treatment of a HW without a permit. Treatment of HW without a permit is subject to a fine of $50,000 per day the violation occurred.

There exist two types of locations for operating the Vyleater; a HW satellite accumulation point (SAP) or a HW 90-day storage area.

Satellite Accumulation Point.

If the Vyleater is located in an established HW SAP that meets all Resource Conservation Recovery Act (RCRA) requirements in Title 40, Code of Federal Regulations (CFR) Section 263.34(c), no additional RCRA record keeping or air-emission standards will apply. The SAP must be at or near the waste generation process and under control of the process operator. The Vyleater will require a substantial amount of space that may prohibit installation in the laboratory (28" x 63" footprint, with adjustable height depending on the size of the collection containers underneath (up to 55-gallon drum), ranging from 73" to 83").

Additionally, the vials are not considered waste until Cytology laboratory personnel complete their slide preparations and patient diagnoses. Once a decision is made to discard the vials, the vials could be relocated to the area where the Vyleater is located for accumulation and shredding. Note, no more than 55 gallons of waste may be maintained in an SAP. This includes the amount of waste awaiting shredding and the amount of waste accumulating in the waste container attached to the Vyleater. Classification of the site as a SAP allows the MTF to install the Vyleater on a loading dock or other secure location where laboratory personnel maintain control of the machine and access to the waste.

90-day Storage Area.

If the Vyleater is not located in an SAP, the RCRA regulations for 90-day storage in Title 40 CFR 262.34(a) will apply. This regulation additionally require compliance with Title 40 CFR 265, Subparts I (Use and Management of Containers), AA (Air Emission Standards for Process Vents), BB (Air Emission Standards for Equipment Leaks), and CC (Air Emission Standards for Tanks, Surface Impoundments, and Containers).

- Subpart I (40 CFR 265.170–178) will apply. Containers must be in good condition, compatible with the waste, closed except when adding or removing waste, located 15 meters from the property line, and the site must be inspected weekly.

- Subpart AA will not apply because use of the Vyleater is not a distillation, fractionation, thin-film evaporation, solvent extraction, or air- or steam-stripping operation.

- Subpart BB (40 CFR 265.1050–1064) requirements will apply. The Title 40 CFR 265.1050(e) excludes equipment that contains or contacts HW for less than 300

hours (hrs) per year from regulation with this Subpart. The Vyleater takes approximately 30 seconds to 2 minutes to consolidate liquid and shred a typical batch of 20-mL vials. A typical batch size is 300 vials. Therefore, the Vyleater would have to process 2,700,000 vials per year to exceed this limit.

$$\left(\frac{300\ hrs}{1\ year}\right)\ x\ \left(\frac{60\ min}{1\ hr}\right)\ x\ \left(\frac{1\ batch}{2\ min}\right)\ x\ \left(\frac{300\ vials}{1\ batch}\right) = 2{,}700{,}000\ vials/year$$

In order to implement this exemption, the record keeping requirement in 40 CFR 265.1064(g)(6) must be maintained. It requires identification, either by list or location of the Vyleater, recorded in a log that is kept in the facility operating record.

• Subpart CC (40 CFR 265.1080–1090) requirements will apply. The Title 40 CFR 265.1080(b)(2) exempts containers of less than or equal to 26 gallons (0.1 meters^3) from regulation with this Subpart. According to Title 40 CFR 265.1087(c)(1)(i) and (f), containers that meet U.S. Department of Transportation (DOT) regulations are considered to meet all container Subpart CC container requirements for this waste stream. Therefore, a closed container greater than 26 gallons may be used to collect the HW from the Vyleater if it complies with all applicable DOT regulations and is kept closed at the site.

Of the two models of Vyleater available (Standard and Enhanced), the Enhanced Vyleater model utilizes a high-torque/low-speed shredder which is better suited for plastic (both pliable and brittle plastic containers), reducing the vials to an unrecognizable mulch. The Standard model utilizes a roll crusher and is better suited to shatter glass containers and brittle plastic.

Management of Containers of Non-Hazardous Waste.

The urine in the sample containers is a non-HW and is also a non-RMW. Once the urine is emptied from the containers, the containers themselves are solid waste and should be disposed as regular trash.

Although not eligible for EPR funding (see section “Eligibility for EPR Funding”), the Vyleater could be used to automate the separation of urine from the sample containers. The liquid discharge from the Vyleater can be connected to a drain so that the urine empties directly to the sanitary sewer, and the shredded sample containers can be collected in a container for disposal as solid waste.

As noted above, the Enhanced Vyleater model utilizes a high-torque/low-speed shredder which is better suited for plastic, reducing the sample containers to

unrecognizable mulch. Because the urine is non-flammable, the explosion-proof model of the Vyleater is not required.

Finally, when using the Vyleater to process urine-specimen containers or other non-HWs that may leave a residue and an odor, purchase and use of the manufacturer's internal conveyor and hopper flushing accessory, and the chemical metering pump accessory (for adding a rinse agent to the water, such as bleach) are desirable options to include.

Eligibility for EPR Funding.

The U.S. Army Medical Command (MEDCOM) uses the EPR data as one of its tools for programming and justifying environmental funding requirements to higher headquarters. This information is also used to program annual funding distributions. It is critical that only legitimate environmental projects be entered into the EPR database. Cost and obligation data must also be accurate.

The preferred method for meeting compliance requirements, reducing operating costs, and maintaining environmental stewardship is through waste minimization projects. The appropriate purchase of the Vyleater equipment as an EPR project would fall under the Army Management System Code 56.42, Non-Recurring Hazardous and Medical Waste (Equipment).

For the management of HW sample vials like the ThinPrep, where the vials are originally collected and disposed of intact without removing the waste, the purchase of the Vyleater is eligible for EPR funding as a waste minimization project. In this example, the use of the Vyleater will reduce the overall amount of HW being disposed of by eliminating the mass/volume of each individual vial and only collect and dispose of the used cyto-preservative solution as an HW. This in turn reduces the costs paid for HW disposal. Whether the purchase and use of the Vyleater will have a return on investment in the amount of time required by MEDCOM for EPR-funding requirements (5 years or less) will depend on the MTF's current costs for management and disposal of the HW vials when compared to management and disposal costs of the same number of vials using the Vyleater.

For management of non-HW urine containers, the Vyleater will shred the containers, separating the urine from the container; however, it is not eligible for EPR funding because the urine is not an HW or an RMW and can be discharged to the sanitary sewer at no cost. Therefore, no reductions in disposal amounts exist for urine. Additionally, there is no reduction in solid waste disposal as the containers themselves are still disposed of as solid waste regardless if they have

been emptied by hand or shredded. In this case, use of the Vyleater does not serve an environmental function. Funding for the purchase of a Vyleater for only non-HW container management would have to come from the MTF's operating budget.

EPR Eligibility Funding Example Calculation.

The following provides estimates and examples of information required to determine the return on investment for implementing the purchase and use of a Vyleater system to manage vials containing HW. Each MTF considering implementation will need to perform site-specific calculations as actual information and costs will vary by location. These calculations must be included in the EPR submission.

Required information to complete the calculations includes: the costs for the current management of the HW vials, costs for management of the same number of HW vials using the Vyleater equipment, and the costs associated with the implementation purchase of the Vyleater equipment.

The following calculations assume that the current management practice for the HW vials is that they are disposed of intact (still containing the methanol-based cyto-preservative) in a 5-gallon bucket prior to disposal as a HW. These calculations mainly focus on the HW disposal costs and do not include other applicable costs such as:

- Differences in the amount of labor (current management procedures and new procedures using the Vyleater). This is because the amount of time for the Vyleater to process a batch of vials is relatively quick (approximately 300 vials per 2 minutes) and is not expected to vary significantly from the current management practice of placing each vial intact into a collection bucket.
- Electrical energy costs for the use of the Vyleater equipment (current management method has no electrical energy costs). Because the equipment is not continuously running but only operates periodically in batches, the cost to run the equipment would not greatly increase the time of the return on investment.
- Weekly preventive maintenance (PM) of the Vyleater equipment. Weekly PM would include labor to clean/brush the conveyor screens and spray/rinse the interior. This is not expected to be labor intensive and would not contribute greatly to increase the return on investment.

- Solid waste disposal costs of the empty/shredded vials. The plastic vials are relatively light and solid waste disposal fees are relatively inexpensive such that this also is not expected to greatly affect the return on investment calculation. Additionally, personnel could research the possibility of finding a recycler for the plastic, which would divert it from the solid waste stream.

While the above costs are not included in this example, MTF personnel should consider adding them when performing their own return on investment calculations, especially if they believe them to be more significant given their specific circumstances.

Assumptions.

- 1,000 specimen vials containing HW cyto-preservative are disposed per week.
- Specimen vials are disposed whole (no removal of the cyto-preservative) by placing each vial in a secondary 5-gallon collection bucket.
- Each 5-gallon bucket will hold approximately 125 specimen vials.
- Number of 5-gallon buckets required per week:

$$\frac{1{,}000\ specimen\ vials}{1\ week}\ x\ \frac{1,5\text{-}gallon\ bucket}{125\ specimen\ vials} = \ 8,5\text{-}gallon\ buckets\ per\ week$$

- Each specimen vial contains approximately 20-mL of HW cyto-preservative.
- Weekly volume cyto-preservative disposed (in 1,000 specimen vials):

$$\left(\frac{1{,}000\ vials}{week}\right)\ x\ \left(\frac{20\ ml}{vial}\right) x\ \left(\frac{0.000264172\ gallons}{1\ ml}\right) = \ 5.28\ gallons\ per\ week$$

- Defense Logistics Agency (DLA) Disposition Services disposal cost for a 5-gallon bucket of D001 HW, $66.80[1].
- Purchase cost of 1, 5-gallon bucket, $15.00.

[1] Avg. cost 5-gallon/D001 HW of all continental United States (CONUS) DLA Disposition Services disposal contracts, April 2016.

- Purchase cost of 1, 55-gallon drum, $200.00.
- DLA Disposition Services disposal cost for a 55-gallon drum of D001 HW, $329.53[2].
- Vyleater Enhanced Model, Explosion-Proof (Model II-Xe), $50,660[3].
- Vyleater Enhanced Model, Standard (Model II-Se), $46,500[4].
- Example Vyleater Options/Accessories (additional options are available)[5]:
  - Basic Conveyor & Hopper Flush, $995 (recommended for non-HW operations only)
  - Chemical Metering Pump, $575 (recommended for non-HW operations only)
  - Hand Held Spray Wand, $595 (for cleaning interior of separating conveyor)
  - Delivery and Set-up of Equipment, $2,995
  - One-Day Onsite Training, $1,500

Cost Estimate, Current Management of HW Vials (Recurring Costs).

HW containers (5-gallon buckets) disposed per year:

$$\left(\frac{8\ buckets}{1\ week}\right)\ x\ \left(\frac{52\ weeks}{1\ year}\right) = 416\ buckets\ per\ year$$

Annual purchase cost HW containers (5-gallon bucket):

$$\frac{416\ buckets}{1\ year}\ x\ \frac{\$15}{1\ bucket} = \$6,240\ per\ year$$

[2] Avg. cost 55-gallon/D001 HW of all CONUS DLA Disposition Services disposal contracts, April 2016.
[3] Recommended for plastic vials and flammable HW. Vyleater equipment pricing is valid until approximately June 2016.
[4] Recommended for plastic containers and non-HW. Vyleater equipment pricing is valid until approximately June 2016.
[5] Vyleater accessories/options pricing is valid until approximately June 2016.

Annual DLA HW (D001) disposal costs (5-gallon buckets):

$$\frac{416\ buckets}{1\ year}\ x\ \frac{\$66.80}{1\ bucket} = \$27{,}788.80\ per\ year$$

Current Management of HW Vials, Annual Recurring Cost:

$$\frac{\$6{,}240}{1\ year} + \frac{\$27{,}788.80}{1\ year} = \$34{,}028.80\ per\ year$$

Cost Estimate, Vyleater Management of HW Vials (Recurring Costs).

Amount HW cyto-preservative solution disposed per year:

$$\frac{5.28\ gallons}{1\ week}\ x\ \frac{52\ weeks}{1\ year} = 274.6\ gallons\ per\ year$$

HW Containers (55-gallon drum) required to collect/dispose cyto-preservative per year:

$$\frac{274.6\ gallons}{1\ year}\ x\ \frac{1\ drum}{55\ gallons} = 5, 55\text{-}gallon\ drums\ per\ year$$

Annual purchase cost HW containers (55-gallon drums):

$$\frac{5\ drums}{1\ year}\ x\ \frac{\$200}{drum} = \$1{,}000\ per\ year$$

Annual DLA HW (D001) disposal costs (55-gallon drums):

$$\frac{5\ drums}{year}\ x\ \frac{\$329.53}{1\ drum} = \$1{,}647.65\ per\ year$$

Vyleater Management of HW Vials, Annual Recurring Cost:

$$\frac{\$1{,}000}{1\ year} + \frac{\$1{,}647.65}{1\ year} = \$2{,}647.65\ per\ year$$

Implementation Costs, Vyleater Management of HW Vials.

Vyleater Enhanced Model, Explosion Proof (Model II-Xe), $50,660

Vyleater Accessory, Hand Held Spray Wand, $595

Delivery and Set-up of Equipment, $2,995

One-Day Onsite Training, $1,500

Vyleater Management of HW Vials, Implementation Cost:

$$\$50{,}660 + \$595 + \$2{,}995 + \$1{,}500 = \$55{,}750$$

Return on Investment, Vyleater Management of HW Vials.

The EPR eligible projects must achieve a 5 year or less return on investment for approval by MEDCOM. Calculate the return on investment (aka, payback-period) by dividing the implementation costs by the difference between the annual recurring costs of the current management method and the annual recurring costs using the Vyleater:

$$\frac{\$55{,}750}{\left[\left(\frac{\$34{,}028.80}{1\ year}\right) - \left(\frac{\$2{,}647.65}{1\ year}\right)\right]} = 1.8\ years$$

CONCLUSION

In the example above, where 1,000 vials per week are expected to be disposed of, the purchase and use of the Vyleater would have a return on investment of approximately 1.8 years. This is well within the required 5-year time frame expected for MEDCOM EPR-eligible projects.

Using the above assumptions and calculations, an estimated minimum amount of HW sample vials disposed per week which would still meet the MEDCOM EPR return on investment of 5 years would be somewhere between 250–300 HW vials. Below that weekly number of vials being disposed of, the purchase and use of the Vyleater equipment would have a return on investment exceeding 5 years.

Although the calculations are not shown here, if the HW sample vials were originally managed by the more labor-intensive process of manually opening and emptying the vials instead of disposing with the contents intact, the difference in labor costs alone would be required to justify the return on investment. This is because there would be no difference in the amount of HW being disposed of (both processes collect and dispose of the cyto-preservative only); the only

difference is in the amount of time it takes to separate the vials from their contents (i.e., manually vs. automated).

Also, the assumptions presented above only address the use of the Vyleater for the processing of the HW vials. The processing of non-HW containers, such as the urine cups, is not addressed because they are not eligible for EPR funding.

Finally, if the Vyleater equipment is purchased with the intent to process both HW and non-HW (i.e., dual use), only the costs for managing the HW vials would be pertinent for performing the calculations for EPR funding return on investment. Equipment for dual usage must be designed to meet the most conservative requirements such as explosion control and liquid discharge collection. The equipment purchased would primarily be that for processing the HW (i.e., need to be explosion-proof) but would include additional accessories for processing non-HW (such as conveyor and hopper-flushing system and a chemical meter pump, which would also have to be explosion proof). These additional accessories would increase the implementation costs and would affect the return on investment.

For this intended dual use of the Vyleater, the manufacturer can install a “double drain arrangement” for the liquid effluent coming from the equipment. This utilizes two hoses: one dedicated to a container to collect the HW and the other dedicated to the sanitary sewer for disposal of the urine and flushing/rinse water. The hoses are connected to a manual diverter valve to allow the operator to switch between the floor drain and the HW collection container, depending on which waste is being processed. In this instance, great care, such as specific operating procedures, labeling of equipment and valves, and training of personnel operating the equipment, will need to be taken to ensure the two wastes are managed separately and correctly (i.e., to avoid discharging HW to the sanitary sewer, or diluting the HW in the collection container with urine/rinse water). Failure to manage the diverter and flush systems properly can result in unpermitted treatment (dilution) of HW which is subject to fines and penalties. If adequate precautions and safeguards cannot be met, the Vyleater should be dedicated to processing only one type of waste, HW or non-HW, and not both.

POINT OF CONTACT

For more help, contact the Waste Management Program at 410-436-3651.

Prepared by: Waste Management Program
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APPENDIX A

REFERENCES

Defense Logistics Agency Disposition Services. Hazardous Waste Contracts Hazardous Waste Disposal Price Database. October 2, 2013. https://www.dlis.dla.mil/HazMat/ (accessed April 11, 2016).

Hologic, Inc. "ThinPrep PreservCyt Solution Safety Data Sheet." Hologic Safety Data Sheet Search. 2016. http://msds.hologic.com/WebViewer/private/document.aspx?prd=PRESERVCYT-SOLN%7E%7EPDF%7E%7EMTR%7E%7EHOL1%7E%7EEN%7E%7E2015-05-26%2006%3A24%3A11%7E%7ETHINPREP%7CTS%20PRESERVCYT%20SOLUTION%7E%7E&__VIEWSTATEGENERATOR=CD1C98A3&CUSTOM3_option=d__~value~&product (accessed April 11, 2016).

S & G Enterprises, Inc. "Accessory US Commercial Price List." Vyleater Vial Disposal System. Germantown, WI: S & G Enterprises, Inc., January 1, 2015.

S & G Enterprises, Inc. "US Commercial Price List." Vyleater Vial Disposal System. Germantown, WI: S & G Enterprises, Inc., January 1, 2015.

S & G Enterprises, Inc. "Vial Crushing & Liquid Disposal." S & G Enterprises, Inc. Vyleater Overview. 2014. http://ramflat.com/wp-content/uploads/2013/03/Vyl_hr05.pdf (accessed April 11, 2016).

GLOSSARY

CFR	Code of Federal Regulations
CONUS	continental United States
DLA	Defense Logistics Agency
DOT	United States Department of Transportation
EPA	Environmental Protection Agency
EPR	Environmental Program Requirements
HW	hazardous waste
hrs	hours
MEDCOM	Medical Command
min	minute
mL	milliliter
MTF	medical treatment facility
PII	personally identifiable information
PM	preventive maintenance
RCRA	Resource Conservation and Recovery Act
RMW	regulated medical waste
SAP	satellite accumulation point